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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/700,932	11/03/2003	Michael Schink	104035.271139	4940

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EXAMINER	
GHALI, ISIS A D	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 10/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/700,932	SCHINK ET AL.	
	Examiner	Art Unit	
	Isis Ghali	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *25 July 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13 and 15-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13 and 15-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The receipt is acknowledged of applicants' amendment filed 07/25/2006.

Claim 14 has been canceled, and claim 26 has been added.

Claims 1-13, and 15-26 are pending and included in the prosecution.

The double patenting rejection over the conflicting claim of US application S.N. 10/735,310 has been withdrawn since the copending application has been abandoned.

The following rejection has been discussed in the previous office action, and are maintained for reasons of record:

Priority

1. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Germany on May 02, 2001. It is noted, however, that applicant has not filed a certified copy of the German application as required by 35 U.S.C. 119(b).

Applicants have not comment on the priority document not being submitted; therefore, the rejection is maintained.

The following new grounds of rejections are necessitated by applicants' amendment:

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1, 2, 5-12, 16 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP '681.

EP '681 teaches drug-releasing system comprised of a drug dispensing polyurethane matrix (abstract). The drug present in amount of 1-10% by weight of the

matrix (col.4, lines 50-51). The drug is dissolved in the matrix that further comprises permeation enhancer (col.5, lines 7-12, 44-45). The matrix is cured, i.e. solvent evaporated (col.5, lines 13-15).

However, EP '681 does not teach the amount of the active ingredient as claimed in claim 1, 7 and 8, the amount of the permeation enhancer as claimed in claim 9, the specific active agents as claimed by claim 6, or the thickness of the matrix as claimed in claims 10-12.

The amount of the active ingredient and the enhancer and the thickness of the matrix do not impart patentability to the claims, absent evidence to the contrary. The specific active agent as claimed in claim 6 does not impart patentability to the claims, absent evidence to the contrary.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have an adhesive matrix with a thickness between 10-3000 μm, and adjust the amount of the active ingredient and the enhancer according to the specific patient need and the drug delivered, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable / ranges involves only routine skill in the art. *In re Aller* 105 USPQ 233.

Response to Arguments

5. Applicant's arguments filed 07/25/2006 have been fully considered but they are not persuasive. Applicants argue that EP '681 does not teach the self adhesive matrix comprising an active ingredient applied in an amount of from 5 μ/cm^2 to 10,000 μ/cm^2 in

dissolved or liquid form, however, the reference teaches the active ingredient in dispersed form.

In response to this argument, applicants' attention is directed to the scope of the rejected claims that is matrix comprising polyurethane and active agent dissolved in the matrix. EP '681 teaches polyurethane absorbs water and dissolves the drug incorporated in the polyurethane (col.5, lines 40-46) leading to polyurethane matrix and dissolved drugs as instantly claimed. The claimed amount of active ingredient is wide range from 5-10.000 μ/cm^2 and one having ordinary skill in the art at the time of the invention would have determined the amount of the drug according to specific patient need and according to drug being used, and it is expected that the amount will fall within the claimed wide rage. Polyurethane is known to be adhesive.

6. Claims 1, 2, 5-8, 10-12, 16 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,839,174 ('174).

US '174 teaches transdermal drug delivery system comprising a polyurethane matrix layer containing 5-50% of active agent dispersed in the matrix in a liquid form (abstract; col.2, lines 55-58; col.4, lines 9-10). The matrix is cured, i.e. solvent evaporated (col.3, lines 24-25). After curing the matrix have a thickness range from 50 to 800 micron (col.6, lines 1-5).

However, US '174 does not teach the amount of the active ingredient as claimed in claim 1, 7 and 8, the amount of the permeation enhancer as claimed in claim 9, the

specific active agents as claimed by claim 6, or the thickness of the matrix as claimed in claims 10-12.

The amount of the active ingredient and the enhancer and the thickness of the matrix do not impart patentability to the claims, absent evidence to the contrary. The specific active agent as claimed in claim 6 does not impart patentability to the claims, absent evidence to the contrary.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have an adhesive matrix with a thickness between 10-3000 μm, and adjust the amount of the active ingredient and the enhancer according to the specific patient need and the drug delivered, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable / ranges involves only routine skill in the art. *In re Aller* 105 USPQ 233.

Response to Arguments

7. Applicant's arguments filed 07/25/2006 have been fully considered but they are not persuasive. Applicants argue that US '174 does not teach the self adhesive matrix comprising an active ingredient applied in an amount of from 5 μ/cm^2 to 10,000 μ/cm^2 in dissolved or liquid form, however, the reference teaches the active ingredient in dispersed form.

In response to this argument, applicants' attention is directed to the scope of the rejected claims that is matrix comprising polyurethane and active agent dissolved in the matrix or in a liquid form. US '174 teaches transdermal drug delivery system comprises

polyurethane matrix and the active agent added in a liquid (col.3, line 21) leading to polyurethane matrix and liquid drugs as instantly claimed. The claimed amount of active ingredient is wide range from 5-10.000 μ/cm^2 and one having ordinary skill in the art at the time of the invention would have determined the amount of the drug according to specific patient need and according to drug being used, and it is expected that the amount will fall within the claimed wide rage. Polyurethane is known to be adhesive.

8. Claims 1, 3, 6-10-12, 16-20, 23, 24 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,958,447 ('447).

US '447 teaches adhesive matrix type transdermal patch and method of its manufacture, wherein the adhesive matrix is loaded with the active substances in a liquid form (abstract; col.2, lines 62-67). The liquid active substance diffuses into the matrix and the matrix remains adhesive over its entire delivery surface that comes in contact the skin (col.3, lines 9-15). The liquid contains 1-33% of active substance and up to 10% of glycerin, ethanol, glycols, mineral oils, and lanoline, which are known to be permeation enhancers (col.11, lines 25-40; col.12, lines 50-62). The transdermal patch is manufactured by depositing the active substance on the adhesive matrix by printing process (col.4, lines 26-41; col.10, lines 53-56). The adhesive matrix can be made of urethanes (col.6, line17).

However, US '447 does not teach the amount of the active ingredient as claimed in claim 1, the specific active agents as claimed by claim 6, or the thickness of the matrix as claimed in claims 10-12.

The amount of the active ingredient and the thickness of the matrix do not impart patentability to the claims, absent evidence to the contrary. The specific active agent as claimed in claim 6 does not impart patentability to the claims, absent evidence to the contrary.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have an adhesive matrix with a thickness between 10-3000 μm, and adjust the amount of the active ingredient and the enhancer according to the specific patient need and the drug delivered, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable / ranges involves only routine skill in the art. *In re Aller* 105 USPQ 233.

Response to Arguments

9. Applicant's arguments filed 07/25/2006 have been fully considered but they are not persuasive. Applicants argue that US '447 does not teach the self adhesive matrix comprising an active ingredient applied in an amount of from 5 μ/cm^2 to 10,000 μ/cm^2 in dissolved or liquid form, however, the reference teaches the active ingredient in dispersed form.

In response to this argument, applicants' attention is directed to the scope of the rejected claims that is matrix comprising polyurethane and active agent dissolved in the matrix or in a liquid form and method of its making comprising applying the active agent by printing to the matrix in dissolved or liquid form followed by evaporating the solvent. US '447 teaches transdermal drug delivery system comprises polyurethane matrix and

the active agent added in a liquid or semi-liquid form (col.10, line 29) by printing (col.10, line 56) leading to polyurethane matrix and liquid drugs as instantly claimed. The claimed amount of active ingredient is wide range from 5-10.000 μ/cm^2 and one having ordinary skill in the art at the time of the invention would have determined the amount of the drug according to specific patient need and according to drug being used, and it is expected that the amount will fall within the claimed wide rage. US '447 teaches the adhesive matrix to be urethane.

The following rejections have been discussed in the previous office action, and are maintained for reasons of record:

10. Claims 3, 4 and 17-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP '681 in view of US 4,915,950 ('950).

The teachings of EP '681 are discussed above.

However, EP '681 does not teach the method by which the active agents are applied to the matrix, dexpanthenol as an active agent as claimed in claim 25, or the amount of the enhancer.

The amount of the enhancer does not impart patentability to the claims, absent evidence to the contrary.

US '950 teaches method of making transdermal drug delivery system wherein the active agents are printed or sprayed in the liquid or dissolved form on the drug carrying layer with a key advantage of having uniform deposition of the of the active

agent on the surface of the drug carrying layer (abstract; col.2, lines 15-16, 48-56; col.3, lines 25-31).

Applicants did not show superior and unexpected results from using dexpanthenol as an active agent in the process of making the patch.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide transdermal drug delivery device comprising polyurethane matrix containing the drug in a liquid form as disclosed by EP '681, and apply the active ingredient to the adhesive matrix by printing or spraying as disclosed by US '950, motivated by the teaching of US '950 that printing or spraying the active agent in the liquid or dissolved form on the drug carrying layer is the key advantage of having uniform deposition of the of the active agent of the surface of the drug carrying layer, with reasonable expectation of having transdermal drug delivery system wherein the drug is uniformly deposited on a polyurethane matrix layer with the consequence of uniform delivery of the active agent.

11. Claims 11-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP '681 in view of US '6,419,935 ('935).

The teachings of EP '681 are discussed above.

However, EP '681 does not teach the thickness of the matrix or dexpanthenol and its concentration in the matrix.

US '935 teaches transdermal patch to deliver comprising an adhesive matrix comprising active agents such as panthenol and D-panthenol that has skin beneficial

effect (abstract; col.3, lines 15-24; col.5, lines 24, 28, 48). The thickness of the adhesive matrix varies from 5-500 microns depending on the active agent to be delivered (col.6, lines 12-17).

The concentration of the panthenol in the matrix does not impart patentability to the claims, absent evidence to the contrary.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide transdermal drug delivery device comprising polyurethane matrix containing the drug in a liquid form as disclosed by EP '681, and adjust the thickness of the matrix between 5-500 micron and incorporate panthenol as the active ingredient as disclosed by US '935, motivated by the teaching of US '935 that thickness of the matrix varies depending on the active agents and the panthenol has beneficial effect on the skin, with reasonable expectation of having a transdermal patch having an adhesive matrix with thickness between 5-500 micron that delivers panthenol and provides beneficial effect to the skin of the user.

12. Claims 3, 4, 9, 10, and 17-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over US '174 in view of US 4,915,950 ('950).

The teachings of US '174 are discussed above.

However, US '174 does not teach the method by which the active agents are applied to the matrix, dexpanthenol as an active agent, or the enhancer and its amount.

US '950 teaches method of making transdermal drug delivery system wherein the drug and a permeation enhancer are printed or sprayed in the liquid or dissolved

form on the drug carrying layer with a key advantage of having uniform deposition of the of the active agent of the surface of the drug carrying layer (abstract; col.2, lines 15-16, 48-56; col.3, lines 25-31; col.7, lines 49-50). The enhancer increases the permeability of the drug to the skin of the user (col.7, lines 55-57).

The amount of the enhancer does not impart patentability to the claims, absent evidence to the contrary.

Applicants did not show superior and unexpected results from using dexpanthenol as an active agent in the process of making the patch.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide transdermal drug delivery device comprising polyurethane matrix containing the drug in a liquid form as disclosed by US '174, and apply the active ingredient to the adhesive matrix by printing or spraying with a permeation enhancer as disclosed by US '950, motivated by the teaching of US '950 that printing or spraying the active agent in the liquid or dissolved form on the drug carrying layer the key advantage of having uniform deposition of the of the active agent of the surface of the drug carrying layer, and the permeation enhancer increases the permeability of the drug to the skin of the user, with reasonable expectation of having transdermal drug delivery system wherein the drug is uniformly deposited on a polyurethane matrix layer with the consequence of uniform enhanced delivery of the active agent to the skin of the user.

13. Claims 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over US '174 in view of US '935.

The teachings of US '174 and US '935 are discussed above.

However, US '174 does not teach dexpanthenol and its concentration in the matrix.

The concentration of the panthenol in the matrix does not impart patentability to the claims, absent evidence to the contrary.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide transdermal drug delivery device comprising polyurethane matrix containing the drug in a liquid form as disclosed by US '174, and adjust the thickness of the matrix between 5-500 micron and incorporate panthenol as the active ingredient as disclosed by US '935, motivated by the teaching of US '935 that thickness of the matrix varies depending on the active agents and the panthenol has beneficial effect on the skin, with reasonable expectation of having a transdermal patch having an adhesive matrix with thickness between 5-500 micron that delivers panthenol and provides beneficial effect to the skin of the user.

14. Claims 2, 4 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over US '447 in view of US '950.

The teachings of the reference are discussed above.

US '447 does not teach, evaporation of the solvent, or applying the active agent by spraying process.

Evaporation of the solvent step does not impart patentability to the claims directed to product, absent evidence to the contrary.

US '950 teaches applying active agent into drug carrying layer by spraying the drug in a liquid or dissolved form, and also teaches the equivalency between spraying and printing.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to produce a transdermal patch comprising self adhesive matrix comprising active agent as disclosed by US '447, and apply the active agent by spraying into the matrix as disclosed by US '950, motivated by the teaching of US '950 that spraying the active agent in the liquid or dissolved form on the drug carrying layer is the key advantage of having uniform deposition of the of the active agent of the surface of the drug carrying layer, with reasonable expectation of having transdermal drug delivery system wherein the drug is uniformly deposited on the adhesive matrix layer with the consequence of uniform delivery of the active agent.

15. Claims 5, 11, 12, 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over US '447 in view of US 5,844,013 ('013).

The teachings of US '447 are discussed above.

However, US '447 does not teach the adhesive matrix made of polyurethane as claimed in claims 5 and 22, or the thickness of the matrix layer as claimed in claims 11 and 12.

US '013 teaches polyurethane foam used in medicine and as a wound dressing because it has self adhesive properties on the skin and can be pulled off painlessly from normal skin (abstract; col.18, lines 14-17). The polyurethane foam forms a layer in the wound dressing having a thickness from 10-1000 micron (col.19, lines 55-57).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to produce a transdermal patch comprising self adhesive matrix made of urethanes and comprising active agent as disclosed by US '447, and replace the urethane with the polyurethane having thickness between 10-1000 micron as disclosed by US '013, motivated by the teaching of US '013 that polyurethane foam of this preferred thickness has self adhesive properties on the skin and can be pulled off painlessly from normal skin, with reasonable expectation of having transdermal patch comprising polyurethane self adhesive matrix delivering active agent to the skin of the patient in need and then is removed painlessly from the skin.

16. Claims 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over US '447 in view of US '935.

The teachings of references are discussed above.

However, US '447 does not teach dexpanthenol and its concentration in the matrix as claimed in claims 13-15.

The concentration of the panthenol in the matrix does not impart patentability to the claims, absent evidence to the contrary.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide transdermal drug delivery device comprising adhesive matrix containing a drug in a liquid form as disclosed by US '447, and incorporate panthenol as the active ingredient as disclosed by US '935, motivated by the teaching of US '935 that panthenol has beneficial effect on the skin, with reasonable expectation of having a transdermal patch having an adhesive matrix that delivers panthenol and provides beneficial effect to the skin of the user.

Response to Arguments

17. Applicant's arguments filed 07/25/2006 have been fully considered but they are not persuasive.

- Applicants traverse the 103 rejections based on EP '681, US '174 and US '447 each in view of US '950 by arguing that US '950 does not teach applying the matrix with active ingredient to the side of the matrix intended for skin contact, and does not teach applying the active agent in an amount of 5 μ/cm^2 to 10,000 μ/cm^2 in dissolved or liquid form.

In response to this argument, it is pointing out that US '950 is relied upon for the solely teaching of the step of applying active agent to the matrix using spraying of the active agent in the liquid or dissolved form. The primary references EP '681, US '174 and US '447 all teach the active agent in the skin contacting layer. The amount of the active agent does not impart patentability to the claims, absent evidence to the contrary.

- Applicants traverse the 103 rejections based on EP '681, US '174 and US '447 each in view of US '935 by arguing that US '935 does not disclose the amount of the active ingredient to be 5 μ/cm^2 to 10,000 μ/cm^2 or where it may be applied, and it does not teach the active agent dissolved or in liquid form.

In response to this argument, it is pointing out that US '935 is relied upon for the solely teaching of the thickness of the matrix and the panthenol as active agent. The primary references EP '681, US '174 and US '447 all teach the active agent in the skin contacting layer. The amount of the active agent does not impart patentability to the claims, absent evidence to the contrary.

- Applicants traverse the 103 rejections based on US '447 each in view of US '031 by arguing that US '031 does not teach the amount of the active agent to be 5 μ/cm^2 to 10,000 μ/cm^2 applied in dissolved or liquid form.

In response to this argument, it is pointing out that US '031 is relied upon for the solely teaching of polyurethane that is missing from US '447. US '447 teaches the drug applied in liquid form. The amount of the active agent does not impart patentability to the claims, absent evidence to the contrary.

Conclusion

18. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 7:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Isis Ghali
Examiner
Art Unit 1615

IG

MICHAEL P. WOODWARD
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